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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,611	11/21/2001	Lorraine Faxon Meisner	121753-1005	4194

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,611	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-18 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-18 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner withdraws the finality of the Office Action, mailed on 7/12/2004, in view of the additional grounds for rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-8, 10-18,21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591)and Taylor et al. (US Pat. 5,308,621)

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any

methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 2, lines 40-47, Column 10, lines 6-17).

Taylor et al. teaches a method of preparing ascorbic acid by heating to dissolve the ascorbic acid and optionally cooling which ascorbic acid is used in topical preparations containing polyhydric alcohols (Column 2, lines 20-26, Column, 3, lines 17-65).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a topical composition comprising at least about 5.0% (w/v) pretreated ascorbic acid, water. Applicant has argued that by "pretreatment" it is meant the definition contained within the Specification (Pg. 7). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the process by which the "pretreated" ascorbic acid is prepared) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van*

Geuns, 26 USPQ2d 1057 (Fed. Cir. 1993). See also In re Morris, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit). In any case, the prior art does teach heating the ascorbic acid to dissolve the same and, optionally cooling, as is disclosed in the Specification under the definition of "pretreatment". As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that none of the prior art suggests having a pH of more than 3.5. The independent claims do not recite a pH of more than 3.5 but a range of 3.5 to 4.1. In any case, the prior art does teach a pH of 3.5-4.1. Herstein teaches that a pH within 3.5 to 4.1 is preferred to

facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 10, lines 6-17). Applicant argues that Murad teaches away from having a pH of more than 3.5 because Murad discloses oral administration, however, Applicant has provided no showing that pH is irrelevant to oral administration. Even in tablets and capsules, pH is a factor which must be accounted for; for example, see Schonmann et al. (US Pat. 4,894,978), Column 6, lines 48-55). Schonmann et al.. was cited solely to refute Applicant's argument that pH is irrelevant to oral administration. Applicant's attempts to refute the disclosure in Schonmann et al. are unpersuasive. Applicant notes that Example 1 is Schonmann discloses a suspension, however, this does not take away from the fact that Schonmann discloses that pH is a factor to be considered in the preparation of the dosage form. Examiner cites to other oral dosage formulations in which pH is relevant to the formulation of the oral dosage form (See Green et al. (US Pat. 3,857,939), Column 1, lines 48-61 (pH of 4.3-5.2 for chewable ascorbic acid tablets); Ruff et al. (US Pat. 5,358,970), Column 1, lines 25-68, Column 2, lines 1-10 (Use of pH stabilizers in tablets and capsules to inhibit degradation of active ingredient). As such, Applicant's arguments do not show that pH is irrelevant to oral administration. Further, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). The mere fact that the preferred embodiment is a capsule or tablet does not teach away from the broad disclosure which discloses as indicated above that ascorbic acid formulations include aqueous formulations. Thus, Applicant has not shown that Murad teaches away from the claimed invention.

With respect to Herstein applicant respectfully points out that emulsions are not solutions, however, Applicant does not indicate the significance of the same. Applicant has provided no evidence that emulsions cannot have a pH. For example, see Woodward et al. (US Pat. 5,358,990), column 7, lines 50-55 (pH of emulsion was measured); Bissett (US Pat. 5,681,852), Column 8, lines 61-63 (disclosing preferred pH of emulsions). Applicant has not provided any evidence which refutes the disclosure of Herstein of 82% protonation or that organoclays which comprise amine salts complex with the ascorbic acid. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Further, Applicant's own Specification discloses the use of amine salts (Specification pgs. 8, 9).

With respect to Applicant's description of Taylor, the portions cited refer to preferred embodiments, which, as indicated above do not constitute a teaching away from a broader disclosure or nonpreferred embodiements. Taylor does not exclude the use of solublized ascorbic acid and Applicant's claims do not explicitly set forth limitations which indicated the amount of water which is contained in the claimed compositions.

Contrary to Applicant's arguments, there is motivation to combine or modify the prior art as indicated in the prior Office Actions. Further, as indicated above, Murad, Herstein and Taylor are properly combinable in the rejection and the combination of all references does suggest an ascorbic acid composition with a pH falling within the range of 3.5 to 4.1

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,3-8, 10-18,21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043) and Taylor et al. (US Pat. 5,308,621)

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of

additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Darr et al. discloses that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remins in the protonated, uncharged form and faciliates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). Darr et al. discloses that at even at a pH of 4.5 a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27).

Taylor et al. teaches a method of preparing ascorbic acid by heating to dissolve the ascorbic acid and optionally cooling which ascorbic acid is used in topical preparations containing polyhydric alcohols (Column 2, lines 20-26, Column, 3, lines 17-65).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a topical composition comprising at least about 5.0% (w/v) pretreated ascorbic acid, water. Applicant has argued that by "pretreatment" it is meant the definition contained within the Specification (Pg. 7). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the process by which the "pretreated" ascorbic acid is prepared) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993). See also In re Morris, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to

interpret claims in applications in the same manner as a court would interpret claims in an infringement suit). In any case, the prior art does teach heating the ascorbic acid to dissolve the same and, optionally cooling, as is disclosed in the Specification under the definition of "pretreatment". As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above to the extent the above is applicable. Applicant's arguments relevant to Herstein are not applicable herein as Herstein is not part of this rejection of ordinary skill in the art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
September 29, 2004

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200 1616